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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,799	01/25/2006	Yasuhiro Kajihara	ACT-004	9645

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KUBOVCIK & KUBOVCIK
SUITE 1105
1215 SOUTH CLARK STREET
ARLINGTON, VA 22202

EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,799	KAJIHARA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-8* is/are pending in the application.

4a) Of the above claim(s) *1-3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 6-8* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 Apr 2009 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 29 Apr 2009, in which claims 4 and 7 are amended to change the scope and breadth of the claim and claim 5 is canceled

This application is the national stage entry of PCT/JP04/11036, filed 27 Jul 2004; and claims benefit of foreign priority document JAPAN 2003-202594, filed 28 Jul 2003. At present an English language translation of this foreign priority document is not of record.

Claims 1-4 and 6-8 are pending in the current application. Claims 1-3, drawn to non-elected inventions, are withdrawn. Claims 4 and 6-8 are examined herein.

Rejections Withdrawn

Applicant's Amendment, filed 29 Apr 2009, with respect to claims 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, of record) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006) has been fully considered and is persuasive with regard to claim 5 and 7, as claim 5 is canceled and amended claim 7 requires cleaving a saccharide of a glycopeptide by sugar hydrolase which cleaves the reducing terminal of an oligosaccharide from a peptide and bonding an aminated complex-type oligosaccharide derivative to the resulting peptide at the same time.

This rejection of claim 5 has been **withdrawn**. This rejection of claim 4 is modified and recited below.

Applicant's Amendment, filed 29 Apr 2009, with respect to claims 6 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, of record) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006) and further in view of Wright et al. (Trends in Biotechnology, 1997, 15, p26-32, of record) has been fully considered and is persuasive with regard to claim 8, as amended claim 7 requires cleaving a saccharide of a glycopeptide by sugar hydrolase which cleaves the reducing terminal of an oligosaccharide from a peptide and bonding an aminated complex-type oligosaccharide derivative to the resulting peptide at the same time.

This rejection of claim 8 has been **withdrawn**. This rejection of claim 6 is modified and recited below.

Claim Objections

Claim 7 is objected to because of the following informalities: in the claims as filed it appears that formula (4) has been partly obscured. Appropriate correction is required.

The following are new or modified grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 4 recites the glycopeptide is "resistant to sugar hydrolase". Claim 6 depends from claim 4 and incorporates all limitations therein. The term "resistant to sugar hydrolase" constitutes new matter because the ordinary definition of "resistant" encompasses the definitions from anything not completely unresistant to completely resistant or completely inert. The specification only describes the instant compound,

which cleaves after 6 hrs, as more resistant than a reference example, which cleaves after for 30 min (test example 1, pages 22-23). This embodiment does not provide sufficient written description support for the scope of the term "resistant to sugar hydrolase".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 and 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 6 recite a glycopeptide comprising an aminated complex-type oligosaccharide of the formula (1) and a thiol group of a peptide binded thereto.

Claim 4 and 6 are indefinite as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the site on the oligosaccharide at which the thiol group of a peptide binds. The specification, for example, at page 21 suggests that this thiol group binds by displacement of the halogen X recited in the claims, however this essential structural relationships is omitted from the invention as recited in the claims. Further, R^1 includes groups that do not have a halogen X.

The term "resistant to sugar hydrolase" in claim 4 is a relative term which renders the claim indefinite. Claim 6 depends from claim 4 and incorporates all limitations

therein. The term "resistant to sugar hydrolase" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The ordinary definition of "resistant" encompasses definitions from anything not completely unresistant to completely resistant or completely inert. For example, the specification discloses the reference example cleaves after for 30 min (test example 1, pages 22-23), which may be interpreted as a small degree of resistance to hydrolysis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, of record) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006).

Rademacher discloses glycoconjugates formed by the process of bonding to an N-haloacetylated glycosamine (column 5, lines 5-17). Rademacher discloses the process of forming a glycopeptide by conjugating the compound Galβ1-4GlcNAcβ1-2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4GlcNAc (column 22, lines 55-65), corresponding to the instant formula (1) wherein R^2 and R^3 are each a group of instant formula (3). Rademacher discloses the haloacetylated glycosylamines reacted with a thiol R'SH to form a thioether (spanning column 12, lines 35-65 and column 13, lines 1-10). The haloacetylation of the glycosamine of compound Galβ1-4GlcNAcβ1-2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4GlcNAc gives the oligosaccharide of instant claim 4 in which R^1 is $-NH-(CO)-(CH_2)_1-CH_2X$ and R^2 and R^3 are the formula (3) as defined in instant claim 4. Rademacher discloses the release of oligosaccharides from glycoproteins by enzymatic methods (column 1, lines 55-56) such as being hydrolyzed an enzyme such as N-glycanase (column 8, lines 15-20), also named PNGase F and defined by the instant specification as a sugar hydrolase at page 9, lines 5-10. It is well known in the art that the specific enzymatic activity of N-glycanase, or peptide-N^4-(acetyl-β-glucosaminyl)-asparagine amidase [EC 3.5.1.52], is to cleave N-acetyl-glucosamine from an aspargine residue.

Rademacher does not specifically disclose the formation of a glycopeptide by bonding said N-haloacetylated glycosamine to the thiol group of a peptide (instant claims 4).

Wong teaches the glycosylation of proteins using N-glycosyl haloacetamides site specific to a cysteine (abstract), or the thiol group of an amino acid in a peptide. Wong teaches the method of conjugating a defined oligosaccharide to cysteine side chains on a protein provides a finer-tuned strategy for synthetic glycosylation of proteins, and suggests the replacement of natural N-linked glycosylation sites with synthetic cysteine-linked ones (page 849, left column, 2nd paragraph in Discussion section). Wong teaches this method allows one to obtain glycoproteins with homogeneous carbohydrate structures attached (page 849, left column, 2nd paragraph in Discussion section). Wong teaches cysteine-linked oligosaccharides mimic the natural N-linkage and can be released from neoglycoproteins, whereas there is no scheme for the release of unprotected sugars from neoglycoproteins (page 849, left column, 4th paragraph in Discussion section). Wong teaches the conjugation of the protein and the oligosaccharide at pH 8.1 under condition that do not denature a protein (page 844, right column, section Alkylation of peptides and proteins).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Rademacher with the teaching of Wong. Both Rademacher and Wong are drawn to the field of conjugating N-glycosyl haloacetamides to proteins. One of ordinary skill in the art would be motivated to combine Rademacher with the teaching of Wong because Wong teaches conjugating a defined

oligosaccharide to cysteine side chains on a protein provides a finer-tuned strategy for synthetic glycosylation of proteins. One of ordinary skill in the art would have a reasonable expectation of success in combining Rademacher with the teaching of Wong because Rademacher discloses the haloacetylated glycosylamines reacted with a thiol R'SH to form a thioether, and a cysteine side chain is a thiol R'SH. Rademacher discloses the release of oligosaccharides from glycoproteins by chemical or enzymatic methods. Wong teaches the replacement of sites of natural glycosylation with synthetic cysteine-linked ones.

Response to Applicant's Remarks:

Applicant's Remarks, filed 29 Apr 2009, have been fully considered and found not to be persuasive.

Applicant notes that Wong is drawn to an oligosaccharide derived from horseradish peroxidase, containing for example a Xyl sugar and a Fucose linked to the glucosamine at the reducing terminal of the oligosaccharide. However, Wong teaches the reaction scheme requires the glucosamine at the reducing terminal of the oligosaccharide (page 846, scheme 1 at top of page), therefore one of ordinary skill in the art would have a reasonable expectation of success in combining the teaching of Wong with the oligosaccharide taught by Rademacher, which also has a glucosamine at the reducing terminal of the oligosaccharide. Further, Wong is drawn to the broader field of biological glycoconjugates (page 843, left column) and not limited to the embodiment of the oligosaccharide derived from horseradish peroxidase and BSA,

therefore it is Rademacher in view of Wong that teaches a glycopeptides that renders obvious the instant invention.

Applicant notes that both Rademacher and Wong are silent as to the glycopeptides having resistance to sugar hydrolase which cleaves the reducing terminal of an oligosaccharide from a peptide. It is well known in the art that N-glycanase cleaves N-acetyl-glucosamine from an aspargine residue. The glycopeptides made obvious by Rademacher in view of Wong do not form a bond between the oligosaccharide and aspargine, but rather to thiol groups. Therefore, despite both Rademacher and Wong being silent as to the comparative resistance of the glycopeptides made obvious by Rademacher in view of Wong to that of an Asn-linked oligosaccharide, one of ordinary skill in the art would reasonably expect that the glycopeptides made obvious by Rademacher in view of Wong would inherently have resistance to this sugar hydrolase, as N-glycanase is known to recognize a different substrate. See also MPEP 2112.01, "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present."

Applicant notes that Wong describes the oligosaccharide cleaved by hydrazinolysis that digests the peptide. However, Rademacher discloses the release of oligosaccharides from glycoproteins by enzymatic methods (column 1, lines 55-56) such as being hydrolyzed an enzyme such as N-glycanase (column 8, lines 15-20), a sugar hydrolase that leaves the aglycone protein intact.

Amended claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, of record) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006) as applied to claims 4, 5 and 7 above, and further in view of Wright et al. (Trends in Biotechnology, 1997, 15, p26-32, of record).

Rademacher in view of Wong renders obvious as above.

Rademacher in view of Wong does not specifically teach the peptide being an antibody (instant claim 6).

Wright teaches all antibodies are glycosylated at conserved positions and the presence of carbohydrate can be critical (abstract). Wright teaches antibodies are glycosylated with a Galβ1-4GlcNAcβ1-2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4(Fuc)-GlcNAc oligosaccharide (page 28, figure 2 at top of page, structure 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Rademacher in view of Wong with the teaching of Wright of the peptide being an antibody. Rademacher, Wong and Wright are all drawn to the field of glycosylation of peptides. One of skill in the art would be motivated to combine Rademacher in view of Wong with the teaching of Wright because Wright teaches all antibodies are glycosylated at conserved positions and the presence of carbohydrate can be critical. One of ordinary skill in the art would have reasonable expectation of success in combining Rademacher in view of Wong with the teaching of Wright because Wright teaches antibodies are glycosylated with an oligosaccharide Galβ1-4GlcNAcβ1-

2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4(Fuc)-GlcNAc which is similar in structure to the oligosaccharide taught by Rademacher Galβ1-4GlcNAcβ1-2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4GlcNAc.

Response to Applicant's Remarks:

Applicant's Remarks, filed 29 Apr 2009, have been fully considered and found not to be persuasive.

Applicant's Remarks regarding Rademacher in view of Wong are addressed as above.

Amended Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, of record) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006) as applied to claim 4 above, and further in view of Lee et al. (US Patent 5,807,943, issued 15 Sep 1998, cited in PTO-892).

Rademacher in view of Wong teaches as above.

Rademacher in view of Wong does not specifically disclose the process for preparing a glycopeptide characterized by cleaving a saccharide of a glycopeptide by sugar hydrolase which cleaves the reducing terminal of an oligosaccharide from a peptide and bonding an aminated complex-type oligosaccharide derivative to the resulting peptide at the same time (instant claim 7).

Lee et al. teaches it is known in the art to synthesize neoglycoconjugates such as neoglycoproteins by using an endo-N-acetylglucosamidinase that performs both sugar

hydrolase and transglycosylation functions (column 1, lines 30-45), or a process that hydolyzes the oligosaccharide and substitutes a new oligosaccharide at the same time.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Rademacher in view of Wong and further in view of Lee et al. to prepare a glycopeptide by cleaving a saccharide of a glycopeptide by sugar hydrolase which cleaves the reducing terminal of an oligosaccharide from a peptide and bonding an aminated complex-type oligosaccharide derivative to the resulting peptide at the same time. See MPEP 2144.04 IV.C., "Selection of any order of mixing ingredients is *prima facie* obvious." Lee et al. teaches a process that hydolyzes the oligosaccharide and substitutes a new oligosaccharide at the same time is known in the prior art in the field of synthesizing neoglycoconjugates. One of ordinary skill in the art would have been motivated to combine Rademacher in view of Wong to replace oligosaccharides from glycoproteins with said aminated complex-type oligosaccharide because Wong teaches this allows one to obtain glycoproteins with homogeneous carbohydrate structures attached and that cysteine-linked oligosaccharides mimic the natural N-linkage and can be released from neoglycoproteins. One of ordinary skill in the art would have had a reasonable expectation of success in performing the steps at the same time because Wong teaches the conjugation of the protein and the oligosaccharide at pH 8.1 under condition that do not denature a protein, and it is well known in the art that N-glycanase functions within the pH range of 7.5-9.5; and that N-glycanase specifically cleaves N-acetyl-glucosamine from an aspargine residue whereas the glycopeptides made obvious by Rademacher in view of Wong do not form

a bond between the oligosaccharide and aspargine but rather to thiol groups through an amido-CH_2-S unit.

Amended Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rademacher et al. (US Patent 5,280,113, issued 18 Jan 1994, of record) in view of Wong et al. (Biochem J., 1994, 300, p843-850, provided by Applicant in IDS filed 06 Jul 2006) and further in view of Lee et al. (US Patent 5,807,943, issued 15 Sep 1998, cited in PTO-892) as applied to claim 7 above, and further in view of Wright et al. (Trends in Biotechnology, 1997, 15, p26-32, of record).

Rademacher et al. in view of Wong et al. and further in view of Lee et al. teaches as above.

Rademacher et al. in view of Wong et al. and further in view of Lee et al. does not specifically teach the peptide being an antibody (instant claim 8).

Wright teaches all antibodies are glycosylated at conserved positions and the presence of carbohydrate can be critical (abstract). Wright teaches antibodies are glycosylated with a Galβ1-4GlcNAcβ1-2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4(Fuc)-GlcNAc oligosaccharide (page 28, figure 2 at top of page, structure 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Rademacher in view of Wong and further in view of Lee et al. with the teaching of Wright of the peptide being an antibody. Rademacher, Wong, Lee et al. and Wright are all drawn to the field of glycosylation of peptides. One of skill in the art

would be motivated to combine Rademacher in view of Wong with the teaching of Wright because Wright teaches all antibodies are glycosylated at conserved positions and the presence of carbohydrate can be critical. One of ordinary skill in the art would have reasonable expectation of success in combining Rademacher in view of Wong with the teaching of Wright because Wright teaches antibodies are glycosylated with an oligosaccharide Galβ1-4GlcNAcβ1-2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4(Fuc)-GlcNAc which is similar in structure to the oligosaccharide taught by Rademacher Galβ1-4GlcNAcβ1-2Manα1-6(Galβ1-4GlcNAcβ1-2Manα1-3)-Manβ1-4GlcNAcβ1-4GlcNAc.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau
Patent Examiner
Art Unit 1623

/Leigh C. Maier/
Primary Examiner
Art Unit 1623